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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,439	10/22/2003	David J. Pinsky	51917-CB-PCT-US/JPW/AJM/A	8415

7590 07/25/2006

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EXAMINER

SZPERKA, MICHAEL EDWARD

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 07/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/692,439

Applicant(s)

PINSKY ET AL.

Examiner

Michael Szperka

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**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,21,25,29,31 and 33-35 is/are pending in the application.
- 4a) Of the above claim(s) 1,2,21,29 and 31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 25 and 33-35 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. Applicant's response and amendments received May 8, 2006 are acknowledged. Claims 3-20, 22-24, 26-28, 30, and 32 have been canceled. Claims 33-35 have been added. Claims 1, 2, 21, 25, 29, 31, and 33-35 are pending in the instant application.

Applicant's election with traverse of Group III, claim 25 and new claims 33-35, as they read on methods of treating reperfusion injuries in the reply filed on May 8, 2006 is acknowledged. The traversal is on the ground that there is no search burden in simultaneously examining all of the claimed inventions. This is not found persuasive because of the reasons of record set forth in the restriction requirement mailed March 3, 2006. Specifically, the patient populations and therapeutic endpoints for the methods of treatment are distinct, and the recited method of identifying compounds for improving ischemic disorders do not require factor IX as was detailed in the prior office action. Further, the instant inventions are classified differently, and a thorough search and consideration of any one invention is not all that would be required to examine the invention of any other group since the instant claimed inventions are not coextensive.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1, 2, 21, 29, and 31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions. Applicant timely traversed the restriction requirement in the reply filed on May 8, 2006.

Applicant's amendment of the claims received May 8, 2006 introduced new claims that have necessitated the following additional restriction requirement.

### ***Election/Restrictions***

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Claims 25, 33, and 35 link inventions V-XI. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claims, claims 25, 33, and 35. Upon the indication of allowability of the linking claims, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise requiring all the limitations of the allowable linking claims will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104. Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicants are advised that if any claims including all the limitations of the allowable linking claims is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

- VI. Claim 34, drawn to a method of treating reperfusion injury by administering peptides or mutated peptides, classified in class 514, subclass 2.
- VII. Claim 34, drawn to a method of treating reperfusion injury by administering peptidomimetics, classified in class 514, subclass 8.
- VIII. Claim 34, drawn to a method of treating reperfusion injury by administering nucleic acids or mutated nucleic acids, classified in class 514, subclass 44.

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- IX. Claim 34, drawn to a method of treating reperfusion injury by administering a small molecule, classified in class 514, subclass 23.
- X. Claim 34, drawn to a method of treating reperfusion injury by administering muteins, classified in class 424, subclass 278.1.
- XI. Claim 34, drawn to a method of treating reperfusion injury by administering antibodies or antibody fragments, classified in class 424, subclass 133.1.

The inventions are distinct, each from the other because of the following reasons:

3. Inventions V-XI are different methods. As such they require unique reagents to practice the claimed invention. The structure of factor IXa muteins, small organic molecules, nucleic acids, peptides, peptidomimetics, and antibodies that bind factor IX are all distinct, and disclosure of any one of these does not render the structure of any other obvious, nor does disclosure of a method of treatment wherein, for example, factor IXa muteins are administered, necessarily anticipate or render obvious other treatment methods such as administering small organic molecules or antibodies. As such, art that anticipates or renders obvious one group would not necessarily anticipate nor render obvious the invention of the other group. Therefore they are patentably distinct.

4. Because these inventions are distinct for the reasons given above, because the literature searches required for Groups V-XI are not coextensive in that art that anticipates or renders obvious the invention of any one group would not necessarily anticipate or render obvious the inventions of the other groups, and because Groups V-XI have acquired a separate status in the art as shown by their different classification

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and divergent subject matter, restriction for examination purposes as indicated is proper.

5. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

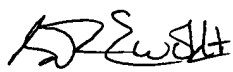
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is 571-272-2934. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael Szperka, Ph.D.  
Patent Examiner  
Technology Center 1600  
July 11, 2006

  
**G.R. EWOLDT, PH.D.**  
**PRIMARY EXAMINER**  
7/18/06